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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,228	02/11/2002	Akira Tsubokura	38331-0003	9520

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EXAMINER	
MARX, IRENE	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,228	TSUBOKURA ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-11 is/are pending in the application.

4a) Of the above claim(s) 1-4 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 5-11 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

The application should be reviewed for errors.

Applicant's election of Group II, claims 5-11 in Paper filed 10/21/03 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 1-4 are withdrawn from consideration as directed to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5-11 are vague, indefinite and confusing in that the claims fail to indicate the conditions required to alter production ratios. It is doubted that merely changing the dissolved oxygen in the culture is sufficient to ensure carotenoid production as claimed. It is apparent that culture medium having particular nutrients is required. Is the culture medium the same or different in each instance? In addition, the extent of "increase" cannot be readily ascertained in the absence of an indication of the baseline production ratio intended.

Claims 5-11 are incomplete in the absence of a recovery step for the product produced.

While there is no specific rule or statutory requirement which specifically addresses the need for a recovery step in a process of preparing a composition, it is clear from the record and would be expected from conventional preparation processes that the product must be isolated or recovered. Thus, the claims fail to particularly point out and distinctly claim the "complete" process since the recovery step is missing from the claims. The metes and bounds of the claimed process are therefore not clearly established or delineated.

Claim 5 is confusing in that the antecedent basis for "the resultant" is unclear.

Claim 11 is vague and indefinite, it that the intended meaning of "the production ratios of... are increased" is uncertain since the baseline is not indicated.

Claims 5, 6, 8-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the production of a plurality of carotenoids under the claimed process conditions with the strains E-396, FERM BP-4283 and A-581-1, FERM BP-4671, and mutants thereof that produce a plurality of carotenoids, does not reasonably provide enablement for the production of a plurality of carotenoids with any microorganism or any mutant of the strains indicated. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

From the record of the present written disclosure only the two specific strains recited have been shown to produce a plurality of carotenoids and have the required characteristics to produce at least astaxanthin and adonixanthin. It cannot be determined from the written disclosure presented whether any of the other carotenoids recited are produced, in what amounts and under which process conditions by other strains, including strains that have 98% or more homology to SEQ ID NO: 1. The only strains having the recited properties are BP-4283 and BP-4671.

In view of the unpredictability of obtaining more strains having the characteristics recited, it would require undue experimentation to obtain further strains to be used in the present process. The term "microorganism" encompasses not only bacteria, but also fungi, yeasts, viruses, protozoa and plant and animal cells. The expectation of success in obtaining further strains having the required properties appears to be low. Ex parte Jackson, 217 U.S.P.Q. 804 (Bd. App. 1982). No specific guidelines are proffered regarding a process of selection of further strains. The process of isolation taught used merely requires plating out soil samples and selecting colonies of orange color. This amounts to no more than an invitation to experiment.

With regard to the "control" of concentration of dissolved oxygen, the as filed specification suggests that specific strains and specific concentrations of dissolved oxygen in the culture medium provide for different results. Also, even when using strains E-396 or A-581-1 it is noted the cryptoxanthin is never produced. See, e.g., specification, page 10 and 14. Also, while E-396 produces asteroidenone, strain A-581-1 does not. Strain Y-1071 produces both of these compounds in at least some amount. However, this strain does not appear to be available to the public. The written disclosure clearly suggests that the production of carotenoids is strain

dependent and unpredictable and not necessarily depend on the concentration of dissolved oxygen.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary to find strains of microorganisms producing a plurality of carotenoids; limited amount of guidance and limited number of working examples in the specification directed to specific strains of an unknown species; the nature of the invention directed to the production of specific carotenoids in increased production ratios; state of the - filed specification; and breadth of the claims, directed to any microorganism. In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Thus, the scope of the claims is not commensurate with the teachings of enablement of the specification.

No claim is allowed.

Claim 7 would be allowable upon resolution of all 35 U.S.C § 112 issues. There would have been no motivation for one of ordinary skill in the art to change the production ratios of a plurality of carotenoids for the strains strains E-396, FERM BP-4283, and A-581-1, FERM BP-4671, and mutants thereof that produce a plurality of carotenoids at the time the claimed invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is 703-308-2922. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0926.

Irene Marx
Primary Examiner
Art Unit 1651